

## **§ 13.40**

should be consulted and why the person's views cannot be furnished to the Board by means other than having FDA arrange for the person's appearance. The Board may, in its discretion, grant or deny the request.

(g) All hearings are to be transcribed. All hearings are open to the public, except that a hearing under §10.20(j)(3) is closed to all persons except those persons making and participating in the presentation and Federal Government executive branch employees and special Government employees. At least a majority of Board members are to be present at every hearing. The executive sessions of a Board, during which a Board deliberates on the issues, are to be closed and are not transcribed. All members of the Board shall vote on the report of the Board.

(h) All legal questions are to be referred to the Chief counsel for FDA for resolution. The Chief Counsel's advice on any matter of procedure or legal authority is to be transmitted in writing and made a part of the record or presented in open session and transcribed.

(i) At the conclusion of all public hearings the Board will announce that the record is closed to receiving information. The Board will provide an opportunity for participants to submit written statements of their positions, with proposed findings and conclusions, and may in its discretion, provide an opportunity for participants to summarize their positions orally.

(j) The Board will prepare a decision on all issues. The decision is to include specific findings and references supporting and explaining the Board's conclusions, and a detailed statement of the reasoning on which the conclusions are based. Any member of the Board may file a separate report stating additional or dissenting views.

### **Subpart C—Records of a Hearing Before a Board**

#### **§ 13.40 Administrative record of a Board.**

(a) The administrative record of a hearing before a Board consists of the following:

(1) All relevant FEDERAL REGISTER notices.

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(2) All written submissions under §13.20.

(3) The transcripts of all hearings of the Board.

(4) The initial decision of the Board.

(b) The record of the administrative proceeding is closed—

(1) Relevant to receiving information and data, at the time specified in §13.30(i); and

(2) Relevant to pleadings, at the time specified in §13.30(i) for filing a written statement of position with proposed findings and conclusions.

(c) The Board may, in its discretion, reopen the record to receive further evidence at any time before filing an initial decision.

#### **§ 13.45 Examination of administrative record.**

(a) The availability for public examination and copying of each document which is a part of the administrative record of the hearing is governed by §10.20(j). Each document available for public examination or copying is placed on public display in the office of the Division of Dockets Management promptly upon receipt in that office.

(b) Lists of nominees and comments submitted on them under §13.10(b)(3) are not subject to disclosure unless they become an issue in a court proceeding.

#### **§ 13.50 Record for administrative decision.**

The administrative record of the hearing specified in §13.40(a) constitutes the exclusive record for decision.

## **PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE**

### **Subpart A—General Provisions.**

Sec.

14.1 Scope.

14.5 Purpose of proceedings before an advisory committee.

14.7 Administrative remedies.

14.10 Applicability to Congress.

14.15 Committees working under a contract with FDA.

### **Subpart B—Meeting Procedures**

14.20 Notice of hearing before an advisory committee.